HEALTH AND SENIOR SERVICES
DIVISION OF HEALTH CARE SYSTEMS ANALYSIS

Standards for Licensure of Ambulatory Care Facilities

Infection Control

Proposed Amendments:	**N.J.A.C. 8:43A-3.7, 14.1 and 14.2**
Proposed Repeals and New Rules	**N.J.A.C. 8:43A-14.3 through 14.7, and 17.1 through 17.6**
Proposed New Rules:	**N.J.A.C. 8:43A-19.8 and 31**

Authorized By:	_____ Clifton R. Lacy, M.D., Commissioner, Department of Health and Senior Services (with the approval of the Health Care Administration Board).
Authority:	N.J.S.A. 26:2H-1 et seq.
Calendar Reference:	Please see Summary below for statement of exception to the rulemaking calendar requirements.
Proposal Number:	PRN 2003-199

Submit written comments by September 5, 2003 to:

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Summary

The Department of Health and Senior Services (the Department) is proposing amendments and new rules to those subchapters dealing with infection control practices in the Licensing Standards for Ambulatory Care Facilities, N.J.A.C. 8:43A. This proposal amends the infection control practices in licensed ambulatory care facilities (N.J.A.C. 8:43A) and a companion proposal, published elsewhere in this issue of the New Jersey Register, amends the infection control practices for licensed general hospitals (N.J.A.C. 8:43G).

The amendments, repeals and new rules which follow are intended to improve the effectiveness of infection control practices in licensed New Jersey health care facilities. The proposed changes are the work of a committee, composed both of representatives from the Department and of infection control professionals from New Jersey's health care industry, which was convened to review and revise licensing standards for infection control in both hospitals and ambulatory care facilities. The primary aim of this effort was to revise the standards, which have not been substantially amended since 1990, to reflect current infection control theory and practice, and thereby reduce the extent of nosocomial infections in New Jersey's health care facilities. However, the proposed amendments, repeals and new rules are also an attempt to carry out the State Legislature's stated intent in P.L. 1998, c.43 to rely less on the certificate of need process and more on licensure and inspections of health care facilities to ensure the provision of high quality health care to New Jersey citizens. In pursuing these dual goals of making the existing standards current and ensuring quality care through the licensure and inspection process, the committee tried to make the existing standards more specific rather than impose a large number of entirely new requirements.

What follows are proposed amendments to N.J.A.C. 8:43A-14, the Infection Control subchapter the Standards for Licensure of Ambulatory Care Facilities. In addition, amendments have been made to the following subchapters, which deal with subjects related to infection control:

N.J.A.C. 8:43A-3.7, Employee Health
N.J.A.C. 8:43A-17, Housekeeping, Sanitation and Safety
N.J.A.C. 8:43A-19, Physical Plant and Functional Requirements

In certain areas entire sections of a subchapter have been recodified to another subchapter. This is the case with the establishment of a new subchapter at N.J.A.C. 8:43A-31, Water Supply and Laundry, that recodifies and elaborates upon existing water supply and laundry requirements that are targeted at reducing the risk of infection. It was the consensus of the committee that the infection control elements of the licensing standards would be better organized if chapter N.J.A.C. 8:43A-14 outlined the core elements of current theory and practice, and that the specific infection control aspects of Central Supply, Housekeeping, and Laundry were better placed in each of those individual subchapters. This is the general organizational technique followed throughout these revisions.

The Committee also proposed another change which, if adopted, will be found not in the chapters listed above but in the respective section on "Employee Health," N.J.A.C. 8:43A-3.7. This is a requirement that not only employees of a facility, but any physician with privileges to practice in a licensed facility, be required to have a Mantoux tuberculin skin test upon employment. The protocols for Mantoux testing have also been updated by the Department's Tuberculosis Control Program to reflect current guidelines from the Centers for Disease Control (CDC), "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities," 1994. The

purpose of these Guidelines, which remain CDC's current recommendations, is to emphasize the importance of a) a hierarchy of control measures, including administrative and engineering controls and personal respiratory protection; b) the use of risk assessments for developing a TB control plan; c) early identification and management of persons who have TB; d)TB screening programs for health-care workers (HCW); e) HCW training and education; and f) evaluation of TB infection-control programs.

At N.J.A.C. 8:43A-19.8, a new rule to the subchapter concerning Physical Plant which requires that when construction or renovation is contemplated in a health care facility, an assessment be made of the project's potential impact on nosocomial infections, and that if necessary preventive measures be undertaken before the construction is initiated.

The major revisions to infection control standards are summarized below:

Subchapter 3 General Requirements

At N.J.A.C. 8:43A-3.7(d), the requirement that employees, including members of the medical staff employed by a health care facility, receive a Mantoux tuberculin skin test has been amended to include all physicians privileged to practice in the facility as well as part-time employees and volunteer staff, in order to strengthen the protections against nosocomial tuberculosis. Amendments to this section also indicate that the frequency of subsequent Mantoux testing as determined by an annual tuberculosis risk assessment of the facility**,** in accordance with current CDC guidelines for preventing the spread of tuberculosis in health care facilities.

Subchapter 14 Infection Prevention and Control Services

N.J.A.C. 8:43A-14.1(b) is amended to change the education and training required for the individual responsible for infection control activities at an ambulatory care facility from the current "a person with a health care background" to "an infection control professional." The infection control professional or a designee must be on site.

To the current requirement in N.J.A.C. 8:43A-14.1(b) that the infection control person have "training or experience in surveillance, prevention, and control of nosocomial infection," a new standard is added at N.J.A.C. 8:43A-14.1(c) that the infection control person become certified in infection control within five years and maintain certification through the Certification Board of Infection Control (CBIC).

N.J.A.C. 8:43A-14.2(a) is amended adding the new position of infection control professional to the membership of the infection control committee. If the ambulatory care facility is operated by an acute care hospital, then the facility may participate in the hospital's Infection Control Program.

N.J.A.C. 8:43A-14.2(b), concerning infection control policies and procedures is amended, in accordance with changes enacted to Hospital Licensing Standards in December 1999, to change the frequency of review of facility policies and procedures from "at least annually" to "every three years or more frequently as necessary," thereby relaxing the requirements for the provider. As in the existing rules, N.J.A.C. 8:43A-14.2(b) itemizes the topics for which the infection control committee shall develop written policies and procedures. New paragraph (b)2 adds HIV/AIDS to the list of reportable conditions.

N.J.A.C. 8:43A-14.2(b)6 states that policies developed for staff training must specifically include infection control.

N.J.A.C. 8:43A-14.2(b) 9 and 10 have been deleted. N.J.A.C. 8:43A-14.2(b)9 addressed sterilization, disinfection, and cleaning practices used in a facility for instruments and utensils, dressings, articles, and surfaces, which include floors, walls, and ceilings. These topics are now addressed and expanded upon at N.J.A.C. 8:43A-14.4. N.J.A.C. 8:43A-14.2(b)10 required policies and procedures for handling, storage, and disposal of regulated medical waste and other solid or liquid waste. These topics are now discussed at N.J.A.C. 8:43A-17.5, which covers collection, storage, and disposal of regulated medical waste, solid waste, and liquid waste in a health care facility.

N.J.A.C. 8:43A-14.3 is amended to update the CDC Guidelines and HICPAC recommendations listed are five current editions of the same Guidelines in the existing licensing standards, and four new Guidelines not currently included. As in the Licensure Standards for Hospitals, CDC web sites are included for the first time along with hard-print publications as an official source of guidelines and recommendations, in recognition of continually changing practice, especially in response to the evolution of antibiotic-resistant organisms. These Guidelines are as follows:

1. **Guideline for Prevention of Catheter Associated Urinary Tract Infections.** This publication contains current CDC recommendations for prevention of urinary tract infections by proper management of temporary indwelling urethral catheters.

2. **Guideline for Prevention of Intravascular Device-related Infections.** This guideline is designed to reduce the incidence of intravascular device-related infections by providing recommendations considered prudent by the Hospital Infection Control Practices Advisory Committee (HICPAC) for the use and maintenance of intravascular devices.

3. **Guideline for Prevention of Surgical Site Infection, 1999.** This document presents the Centers for Disease Control and Prevention (CDC's) recommendations for prevention of surgical site infections. The document is primarily intended for use by surgeons, operating room nurses, infection control professionals, and other personnel directly responsible for prevention of nosocomial infections.

4. **Guidelines for Prevention of Nosocomial Pneumonia.** These recommendations, intended for use by personnel who are responsible for surveillance and control of infections in acute-care hospitals, address common problems encountered by infection control practitioners regarding the prevention and control of nosocomial pneumonia in hospitals.

5. **Guideline for Handwashing and Hospital Environmental Control, 1985.** This guideline provides CDC recommendations for handwashing, as well as for cleaning and disinfecting a hospital's inanimate environment.

6. **Guideline for Infection Control in Hospital Personnel (1998).** This guideline updates the CDC guideline of the same title from 1983. The revisions focus on the epidemiology of infections known to be transmitted in health care settings, and on methods for reducing the transmission of infections from patients to health care personnel and from personnel to patients.

7. **Guideline for Isolation Precautions in Hospitals (1996).** HICPAC and CDC have revised this guideline to assist hospitals in maintaining up-to-date isolation practices.

8. **Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health Care Facilities, (MMWR 1994).** These guidelines replace and update all previously published guidelines for prevention of *Mycobacterium tuberculosis* in health care facilities.

9. **HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance, (1995).** Since 1989, a rapid increase in the incidence of infection by vancomycin-resistant enterococci (VRE) has been reported by US hospitals. This report presents recommendations of HICPAC for preventing and controlling the spread of vancomycin resistance, with a special focus on VRE.

N.J.A.C. 8:43A-14.4(a) adds the requirement that methods for processing reusable medical devices conform to the latest publication from the Association for the Advancement of Medical Instrumentation (AAMI), and lists the current publications. This is an example of the proposed revisions making the standards more specific. The publications are as follows:

1. "Good Hospital Practice: Steam Sterilization and Sterility Assurance," ST 46: This recommended practice provides guidelines for steam sterilization in hospitals and similar health care facilities. These practice standards sets forth guidelines for facility design and work practices to assist health care personnel in developing procedures to achieve and maintain the sterility assurance level of devices sterilized by saturated steam under pressure.

2. “Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use,” ST 37: The guidelines contained in this document are intended to assist health care personnel in: assuring the sterility of devices and materials processed by flash steam sterilization; maintaining the sterility of processed items until the point of use; and promoting good infection control and safe handling practices. Flash sterilization can be performed in various areas of the health care facility, including the operating room, labor / delivery room, and emergency / trauma room.

3. “Safe Use and Handling of Gultaraldehyde-based Products in Health Care Facilities,” ST 58: This recommended practice provides guidelines for the safe use and handling of Gultaraldehyde as a disinfectant and sterilant in health care facilities by defining facility design considerations, work practices, and engineering controls including ventilation recommendations, that will help reduce personnel and patient exposure to Glutaraldehyde.

4. “Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities,” ST 33: These guidelines are intended to increase assurance of sterility by identifying the special considerations that apply to this packaging method and by providing recommendations on the proper use of the container system. These recommendations address cleaning, decontamination, preparation, assembly, loading, quality assurance, sterile storage, transport and process performance.

5. “Steam Sterilization and Sterility Assurance Using Table Top Sterilizers in Office-based, Ambulatory Care, Medical, Surgical and Dental Facilities,” ST 42R: This recommended practice specifically addresses; functional and physical design criteria for work areas; staffing, education and other personnel considerations; sterilization processing procedures; installation, care and maintenance of table top steam sterilizers; quality control and continuous quality improvement.

6. “Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Non-clinical Setting,” ST 35: The biological decontamination process includes through cleaning, and whenever necessary for personnel or patient safety, appropriate application of a microbiological process (disinfection or sterilization) This recommended practice addresses; design criteria for decontamination areas; staffing, education and other personnel considerations; immediate handling of contaminated items at the point of use; transport of contaminated items, and decontamination processed.

7. “Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness,” ST 41R: This recommended practice specifically addresses; design considerations for EO sterilization processing areas; staff qualifications, education, and other personnel considerations; processing procedures; installation, care, and maintenance of EO sterilizers; and quality control.

8. “Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes,” The reprocessing protocol presented in this recommended practice outlines basis steps to clean and process gastrointestinal endoscopes. It covers preparing the endoscopes for cleaning, leak testing, cleaning, rinsing, high level disinfection, drying and storage.

N.J.A.C. 8:43A-14.4(b) provides the addresses of the AAMI and of the Society of Gastroenterology Nurses and Associates, Inc., from which the publications above can be obtained.

N.J.A.C. 8:43A-14.4(c) concerning “scrupulous cleaning” and categorization (that is, critical, semicritical, noncritical) of devices is being required prior to sterilization or disinfection. Invasive devices are to be sterilized or disinfected in accordance with manufacturer’s “written” recommendations or according to infection control committee policy. N.J.A.C. 8:43A-14.4(d) states that the efficacy of chemicals used for disinfection shall be verified by testing if a reliable test is available for an ambulatory setting. N.J.A.C. 8:43A-14.4(e) identifies documentation regarding a facility’s sterilization process which must be kept for a t least one year; these items include time, temperature, and pressure readings, the date, load number, and contents of each load. N.J.A.C. 8:43A-14.4(f) requires that the manufacturer’s instructions for cleaning, sterilization, and testing of equipment shall be readily available to employees; N.J.A.C. 8:43A-14.4(g) requires that sterilized materials must be handled and stored so as to preserve sterility; N.J.A.C. 8:43A-14.4(h) states that the expiration date of sterile supplies shall not exceed the shelf life recommended by the manufacturer of the packaging, and that the facility have a policy to retrieve outdated supplies. N.J.A.C. 8:43A-14.4(i) requires that a facility using an event-related sterility program shall document proper transportation, storage, and rotation of the product, and maintenance of sterile pack integrity.

The existing requirements for sterilized materials (formerly N.J.A.C. 8:43A-14.4(g)) is deleted and replaced at N.J.A.C. 8:43A-14.4(j) with more specific requirements that include criteria regarding “event related sterility programs”. These added criteria include a continuous quality plan that documents facility compliance with proper transport, storage, rotation and maintenance of sterile products and/or packaging. N.J.A.C. 8:43A-14.4(k) requires sterilization equipment to be installed and operated in accordance with the manufacturer’s written instructions.

N.J.A.C. 8:43A-14.4(l) (recodified from (k)) delineates strict conditions under which single use patient care items may be reprocessed, in house or by an outside party, methods for doing so, and documentation to be maintained. Such items must be reprocessed either according to the manufacturer’s written instructions, and/or in accordance with the following Food and Drug Administration (FDA) regulations:

1. “Pre-market notification, registration and listing, 21 CFR, Part 807: This regulation requires that owners and operators of establishments who process single use devices must register their establishment with the Food and Drug Administration (FDA) and list each type of device processed.

2. “Quality Systems Regulations,” 21 CFR Part 807: Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation that governs the methods, facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices.

New language at N.J.A.C. 8:43A-14.4(m) establishes standards for outside reprocessing centers. These requirements include unified policies and procedures approved by all participating facilities in the network in conjunction with infection control managers (N.J.A.C. 8:43A-14.4(m)1); inventorying and pre-cleaning of instruments prior to transport (N.J.A.C. 8:43A-14.4(m)2); decontamination, assembly and sterilization performed in accordance with manufacturer’s written recommendations (N.J.A.C. 8:43A-14.4(m)3; processing facility records maintained (for example, sterilization logs, biological monitoring documentation consistent with 14.5(a)) (N.J.A.C. 8:43A-14.4(m)4); and, the transport of sterile product using disinfected, impervious, sealed or locked containers (N.J.A.C. 8:43A-14.4(m)5).

New language at N.J.A.C. 8:43A-14.4(n) establishes criteria for examining and repairing reusable linens (identical to criteria for hospitals as set forth at N.J.A.C. 8:43G-8.7(c)).

N.J.A.C. 8:43A-14.5 is repealed and a new rule is proposed spelling out each step of the sterilization process in detail, with the aim of making the sterilization process more precise and effective. However, the same general process is already required in the existing N.J.A.C. 8:43A-14.5 (a) through (e). Therefore rather than additional requirements, these are merely a more specific description of existing standards. N.J.A.C. 8:43A-14.5(a)1 through 4 outline the biological monitoring schedule for each type of sterilization agent (that is, ethylene oxide, peracetic acid, low temperature gas plasma, steam). N.J.A.C. 8:43A-14.5(a)5 requires a biological monitor with live spores to be performed following repair or breakdown of the sterilization equipment. N.J.A.C. 8:43A-14.5(a)6 requires the sterilization process for implantables to use a biological monitor and to await the results prior to the use of the implantables. N.J.A.C. 8:43A-14.5(b) requires that the biological indicator to be used be applicable to the sterilization process and stored consistent with manufacturer’s recommendations. N.J.A.C. 8:43A-14.5(b)1 requires a rapid read out biological monitor to be incubated, for a time period in accordance with the manufacturer’s written instructions, to obtain a spore kill reading. N.J.A.C. 8:43A-14.5(b)2 requires a chemical indicator to be used that is applicable to the sterilization process to be used (that is, steam, ethylene oxide, gas plasma, peracetic acid). N.J.A.C. 8:43A-14.5(b)3 requires a daily prevacuum air removal test to be performed on each prevacuum sterilizer and following repair or breakdown of the prevacuum sterilizer. N.J.A.C. 8:43A-14.5(b)4 requires effective corrective action, including retesting and recalls if necessary, and documentation in the event of a positive

biological test of a sterilizer. N.J.A.C. 8:43A-14.5(b)5 requires the individual responsible for reprocessing medical instruments to be certified by a national certification program within two years of employment. N.J.A.C. 8:43A-14.5(b)6 requires personnel involved in the use of ethylene oxide to have appropriate licensure from the New Jersey Department of Environmental Protection. New language in N.J.A.C. 8:43A-14.5(c) establishes criteria for “just in time” or “immediate use only” cleaning techniques ("flash sterilization”) which are identical to criteria being established for hospitals (as set forth at proposed N.J.A.C. 8:43G-8.7(d)). N.J.A.C. 8:43A-14.5(d) requires immediate notification to the receiving facility by an outside reprocessing center in the event of a positive biological result.

Existing N.J.A.C. 8:43A-14.6, which deals with regulated medical waste, has been repealed and the topic moved to Subchapter 17, Housekeeping, Sanitation, and Safety, where it can be found at N.J.A.C. 8:43A-17.5, Regulated medical waste and solid waste management. New section N.J.A.C. 8:43A-14.6, Maintenance of sterile processing environment, relates to N.J.A.C. 8:43A-14.4 through 14.5 immediately preceding it, and addresses the clean processing of environmental surfaces in the areas in a health care facility which are used for decontamination. N.J.A.C. 8:43A-14.6(a) 1 through 5 requires that hard floor surfaces, walls, ceilings, ventilation systems, storage shelves, and all horizontal surfaces be kept clean. N.J.A.C. 8:43A-14.6(b) states that clean work areas must be kept separated from contaminated ones.

N.J.A.C. 8:43A-14.7, Disposition of tissue, has been repealed. This topic is now covered under N.J.A.C. 8:43A-17.5(b), which states that a health care facility shall comply with the provisions of the Comprehensive Regulated Medical Waste Management Act. Under this act, Class II regulated medical waste includes body organs and tissue. In the proposed rule, N.J.A.C. 8:43A-14.7 is now reserved.

Subchapter 17. Housekeeping, Sanitation and Safety

N.J.A.C. 8:43A-17.1(a) is repealed and a new rule proposed to reorganize this section, in order to begin, in subsection (a), with the establishment of policies and procedures. N.J.A.C. 8:43A-17.1(b) requires a written schedule for the frequency of cleaning for all areas, equipment, and structures within its scope of responsibility. N.J.A.C. 8:43A-17.1(c),(d) and (e) require that a list be maintained of all cleaning and disinfecting agents, and all pesticides and herbicides used in the facility, along with their Materials Safety Data Sheet. N.J.A.C. 8:43A-17.1(f) states that pesticides shall be applied according to State pesticide control regulations at N.J.A.C. 7:30.

Existing N.J.A.C. 8:43A- 17.2 has been repealed because it is now addressed at N.J.A.C. 8:43A-17.1(b) and 17.2(b). N.J.A.C. 8:43A-17.2(a) states that a single individual must be responsible for housekeeping/environmental service, but that the person may be hired by contract. N.J.A.C. 8:43A-17.2(b) outlines the timetables and subject matter of training for housekeeping staff.

Existing N.J.A.C. 8:43A-17.3, Patient care environment, and 17.4, Waste removal, are repealed and replaced with new sections. Existing N.J.A.C. 8:43A-17.4, which deals with waste removal, has been relocated as a new section N.J.A.C. 8:43A-17.5, Regulated medical waste and solid waste management.

The majority of the specific environmental and housekeeping standards in new N.J.A.C. 8:43A-17.3, Housekeeping patient services, and 17.4, Environmental patient care services, already exist in N.J.A.C. 8:43A-17.3, Patient care environment, of the current standards. New standards are as follows: N.J.A.C. 8:43A-17.3(d) requires housekeeping supplies to be approved by the Infection Control Committee and used according to the manufacturer's written instructions. N.J.A.C. 8:43A-17.3(e) requires bathrooms to be kept clean and in good repair. N.J.A.C. 8:43A-17.3(f) requires toilet tissue, soap and disposable paper towels or air driers in each bathroom at all times. Each handwashing sink is also required to have soap and either paper towels or air driers. N.J.A.C. 8:43A-17.3(g) requires reusable hand-cleanser dispensers to be cleaned inside and out and does not permit the reuse of disposable hand cleanser dispensers. N.J.A.C. 8:43A-17.3(h) requires carpeting to be kept clean and in good condition and not frayed or torn. N.J.A.C. 8:43A-17.3(i) through (k) require that windows and screens, curtains, walls, ceilings, and vents be clean and in good condition. N.J.A.C. 8:43A-17.3(l) requires safe and effective control measures to minimize insect and pest infestations. N.J.A.C. 8:43A-17.3(m) requires nonskid floor wax to be used for all waxed floors. N.J.A.C. 8:43A-17.3(n) discusses the use of stuffed animals and communal toys, and N.J.A.C. 8:43A-17.3(o) prohibits plants and flowers in patient treatment areas or in sterile processing areas.

N.J.A.C. 8:43A-17.4 establishes the environmental conditions that must be met for patient care services. These conditions include: accurate and visible thermometers in areas where perishables and other items subject to deterioration are present (for example, refrigerators, freezers, storerooms), as well as 12 month record-keeping (N.J.A.C. 8:43A-17.4(a)1), article storage to be above the floor and away from walls, ceilings and air vents to facilitate cleaning (N.J.A.C. 8:43A-17.4(a)2), separate refrigerators for medications, laboratory specimens, and food (N.J.A.C. 8:43A-17.4(a)3), fire-resistant and flameproof draperies, upholstery and other fabrics or decorations (N.J.A.C. 8:43A-17.4(a)4), the prohibition against latex foam pillows (N.J.A.C. 8:43A-17.4(a)5), equipment requiring drainage to be drained to a sanitary connection in accordance with State and local codes (N.J.A.C. 8:43A-17.4(a)6), a maximum indoor temperature (in warm weather) of 82 degrees Fahrenheit and a written heat emergency plan (N.J.A.C. 8:43A-17.4(a)7), an indoor minimum temperature of 72 degrees Fahrenheit when patients are in the facility (N.J.A.C. 8:43A-17.4(a)8), the prohibition of throw or scatter rugs (N.J.A.C. 8:43A-17.4(a)9), all equipment requires unobstructed space provided for operation (N.J.A.C. 8:43A-17.4(a)10), prohibition of storage of combustible materials in heater rooms or within any open basement heater (N.J.A.C. 8:43A-17.4(a)11), flammable materials are to be stored outside the building, with minimum supplies stored in closed, locked metal cabinets or containers in a non-patient area (N.J.A.C. 8:43A-17.4(a)12), furnishings are required to be clean and in good repair and mechanical equipment is to be in good working order (N.J.A.C. 8:43A-17.4(a)13),

mattresses, pillows, coverings, and bedsprings be kept clean, and be disinfected following discharge of each patient (N.J.A.C. 8:43A-17.4(a)14), all equipment and environmental surfaces be kept clean to sight and touch (N.J.A.C. 8:43A-17.4(a)15), and N.J.A.C. 8:43A-17.4(a)16 requires that when an area of a health care facility is undergoing renovation or new construction, measures be taken to contain dust, and to redirect traffic in patient areas.

N.J.A.C. 8:43A-17.5 and 17.6 have been relocated as N.J.A.C. 8:43A-31.1 in a new Subchapter 31, Water Supply and Laundry. See discussion under Subchapter 31, below.

N.J.A.C. 8:43A-17.4**,** Waste removal, of the existing rules has been expanded into a new N.J.A.C. 8:43A-17.5, Regulated medical waste and solid waste management. As mentioned earlier in this summary, existing N.J.A.C. 8:43A-14.6, Regulated medical waste, and 14.7, Disposition of tissue, as dealing with related subjects, have also been recodified at new section N.J.A.C. 8:43A-17.5.

N.J.A.C. 8:43A-17.5(a) requires that policies and procedures be established and enforced for the collection, safe storage, and disposal of solid, liquid, and regulated medical waste. N.J.A.C. 8:43A-17.5(a)1 states that plastic bags of sufficient strength be used for solid waste removal from patient care units. N.J.A.C. 8:43A-17.5(a)2 requires that outside storage containers for solid waste be kept covered, unless used for cardboard, recyclables, or construction materials. N.J.A.C. 8:43A-17.5(a)3 states that garbage compactors shall be located on an impervious pad which is graded to a drain connected to the sanitary sewer system. N.J.A.C. 8:43A-17.5(a)4 requires that solid waste that is not regulated medical waste be disposed of as approved by the NJDEP. N.J.A.C. 8:43A-17.5(a)5 states that indoor storage containers for solid waste be fireproof, and kept covered if necessary to control odors. N.J.A.C. 8:43A-17.5(a)6 requires that solid waste be stored in an area that is kept clean, and be collected frequently enough to avoid odors, flies, rodents, and that waste not overflow its containers.

N.J.A.C. 8:43A-17.5(b) requires that facilities comply with the provisions of N.J.S.A. 13:1E-48.1 et seq., the Comprehensive Regulated Medical Waste Management Act.

Under proposed N.J.A.C. 8:43A-17.5(c) all liquid waste shall be collected, stored, and disposed of in accordance with the rules of the New Jersey Department of Environmental Protection.

Subchapter 19. Physical Plant and Functional Requirements

N.J.A.C. 8:43A-19.1 through 19.7 have not been amended. These sections identify the building codes and architectural standards which apply to renovation or new construction of ambulatory care facilities; provide a “grandfathering” exemption for

construction or alterations completed prior to the effective date of N.J.A.C. 8:43A; discuss plan review fees; handicapped accessibility; and specific requirements for ambulatory care facilities with fewer than four employees.

A new section, N.J.A.C. 8:43A-19.8, has been added to this subchapter, requiring health care facilities to assess the potential impact on infection control of any construction or renovation contemplated by the facility, and to address the risk before, during, and at completion of the project.

Subchapter 31. Water Supply and Laundry

N.J.A.C. 8:43A-17.5, Water supply, and 17.6, Laundry services, of the existing Standards for Licensure of Ambulatory Care Facilities have been relocated as N.J.A.C. 8:43A-31.1 and 31.2 in a new Subchapter 31, Water Supply and Laundry. N.J.A.C. 8:43A-17.5 has been recodified as 31.1(a). In N.J.A.C. 8:43A-31.1(b), the upper and lower limits for hot water, which had been 95 degrees Fahrenheit to 120 degrees Fahrenheit for handwashing and 95 degrees Fahrenheit to 110 degrees Fahrenheit for bathing, have been made 105 degrees Fahrenheit to 120 degrees Fahrenheit for both handwashing and bathing, to be consistent with the standard now recommended by the American Institute of Architects' Guidelines for Design and Construction of Hospital and Health Care Facilities, which may be obtained from the American Institute of Architects, 1735 New York Avenue, NW, Washington, D.C. 2006 (as set forth at A7.31.E3), and to prevent Legionella and other waterborne pathogens.

The remainder of the chapter closely follows the material in the existing or proposed companion infection control amendments to the Licensing Standards for Hospitals (N.J.A.C. 8:43G), N.J.A.C. 8:43A-13.9 through 13.15. The intent of introducing this degree of specific detail in the amendments to both the hospital licensing rules and this subchapter is to eliminate the storage and processing of laundry as a potential source of nosocomial infection.

N.J.A.C. 8:43A-8:43A-31.2, Laundry policies and procedures. N.J.A.C. 8:43A-31.2(a) requires the laundry service to have written policies and procedures, reviewed and revised every three years or more frequently if needed. There shall be a specific policy for handling soiled laundry. N.J.A.C. 8:43A-31.2(b) states that all used laundry shall be considered contaminated and handled according to written policies approved by the infection control committee.

N.J.A.C. 8:43A-8:43A-31.3, Laundry patient services. N.J.A.C. 8:43A-31.3(a) requires soiled laundry to be collected and removed from patient care areas in a manner so as to prevent leakage. N.J.A.C. 8:43A-31.3(b) requires laundry carts to be kept clean and in good repair, and identified as for clean or soiled laundry. N.J.A.C. 8:43A-31.3(c) states that clean linen shall be stored in an enclosed area, and transported in covered carts. N.J.A.C. 8:43A-31.3(d) states that bedding and clothing provided to staff and patients shall be clean and in good repair. N.J.A.C. 8:43A-31.3(e) states that mop heads be washed separately from other laundry, and that if mop heads

are washed in machines used for other laundry, that the machine be put through a wash cycle with bleach after washing mop heads.

N.J.A.C. 8:43A-8:43A-31.4, Laundry space and environment. N.J.A.C. 8:43A-31.4(a) requires soiled laundry to be stored in containers in a clean and ventilated and vermin free area, separate from other supplies. It must be collected often enough so it does not overflow the containers. N.J.A.C. 8:43A-31.4(b) states that soiled laundry be handled only in designated areas. N.J.A.C. 8:43A-31.4(c), (d), and (e) deal with requirements for laundry chutes. N.J.A.C. 8:43A-31.4(f) &)g) state that if the facility has either an in-house laundry or a limited use home-style laundry, the walls, floor, and ceiling of the area shall be kept clean and in good repair. N.J.A.C. 8:43A-31.4(h) states that if a facility contracts with a commercial laundry service, the facility itself shall have areas for sorting and receiving, and that they must be kept clean and in good repair. N.J.A.C. 8:43A-31.4(i) requires a written schedule for removing lint from laundry areas on a regular basis N.J.A.C. 8:43A-31.4(j) states that soiled laundry and clean linen shall be kept separate, and that if the facility has an in-house laundry, the flow of ventilation shall be from clean to soiled areas.

N.J.A.C. 8:43A-8:43A-31.5, Laundry supplies and equipment. N.J.A.C. 8:43A-31.5(a) requires the facility to have on site an ample supply of the linens they use – sheets, pillowcases, blankets, towels, washcloths, and scrub suits, etc. N.J.A.C. 8:43A-31.5(b) requires facilities to provide laundered scrub suits in surgical suites, PACU, central processing, and other areas as determined by facility policy. In the event that the facility has an in-house laundry, N.J.A.C. 8:43A-31.5(c) requires an established protocol to be followed to reduce the number of bacteria in the fabrics. N.J.A.C. 8:43A-31.5(d) states that a facility laundry service must monitor and document the following: unsafe objects found, linen supply, stained linens, and pH. This last item shall be monitored by "sour testing" of random samples of laundry batches, to ensure neutralization of alkaline residues from detergents. Fabric pH shall be kept at 7.0 or below when "built," or alkaline, detergents are used.

N.J.A.C. 8:43A-8:43A-31.6, Laundry staff education and training. N.J.A.C. 8:43A-31.6(a) states that if applicable, a laundry staff education program shall be as outlined in the Hospital Licensing Standards at N.J.A.C. 8:43G-5.9. This section of the hospital standards outlines steps for developing a written plan of staff education, including orientation, use of new equipment, individual staff requests for educational programs, supervisor judgements about staff education needs, statutory requirements relevant to the specific service, and areas identified by the quality assurance program as needing staff educational programs. N.J.A.C. 8:43A-31.6(b) states that if applicable, orientation for new laundry employees shall include protocols for handling soiled laundry and clean linen.

N.J.A.C. 8:43A-8:43A-31.7, Laundry quality improvement methods. N.J.A.C. 8:43A-31.7(a) requires a quality improvement (QI) program for the laundry service which is coordinated with the facility's overall QI program, and includes collecting data to identify problems, and recommending and implementing corrective actions. N.J.A.C.

8:43A-31.7(b) states that facilities which contract with a commercial laundry service shall employ QI measures to ensure that the laundry standards of Subchapter 31 are met.

Because a 60-day comment period has been provided on this notice of proposal, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Department's licensing standards establish the minimum standards of care for all New Jersey licensed health care facilities. The proposed infection control amendments, repeals and new rules reflect a commitment by the Department to be responsive to a changing health care environment and technology, and to protect the quality of care by ensuring that licensing standards reflect current theory and practice. The Department anticipates that the social impact will be favorable, since the proposed amendments, repeals and new rules, if adopted and followed, should have the effect of reducing the incidence of nosocomial infection in licensed New Jersey health care facilities.

Economic Impact

In some respects the proposed amendments and new rules are less restrictive than current rules. Throughout these proposed amendments and new rules, for example, the requirement that written policies and procedures be revised and updated annually has been changed to every three years. This will be less burdensome to all licensed ambulatory care facilities, and recognizes both that staff in health care facilities are generally too busy to spend time revising policies every year, and that it is not necessary because patterns of care do not change fast enough to justify it. This relaxation of timeframes should free up staff time for more urgent matters, and may thereby have a positive economic impact on New Jersey's licensed ambulatory care facilities.

In some instances, however, licensed ambulatory care facilities will have to expend additional time and money to comply with the proposed standards. Ambulatory care facilities will have to spend additional monies to make the shift from having the person responsible for infection control be simply "a person with a health care background" (N.J.A.C. 8:43A-14.1(b)) to being "an infection control professional" with "education or training in surveillance, prevention, and control of nosocomial infections." These requirements for more specialized education and training may require higher salaries.

However, it is the intent and purpose of the proposed amendments, repeals and new rules that such up-front and quantifiable additional expenses will result in a decrease in nosocomial infection, and thereby generate larger though less quantifiable savings, both to the health care facilities involved and to society in general.

Federal Standards Statement

The proposed amendments, repeals and new rules do not impose standards on ambulatory care facilities in New Jersey that exceed those contained in applicable Federal standards, therefore, a Federal standards analysis is not required. The applicable Federal standards may be found at 42 C.F.R. §416, for ambulatory care facilities, and at 42 C.F.R. §405.2100, Subpart V, for end-stage renal disease.

Jobs Impact

The proposed amendments and new rules will not result in any loss of jobs in the healthcare industry or elsewhere in the economy. They may result in some moderate increase in infection control staffing in licensed ambulatory care facilities.

Agriculture Industry Impact

The proposed amendments, repeals and new rules will have no impact on the agriculture industry.

Regulatory Flexibility Analysis

The majority of licensed ambulatory care facilities in New Jersey employ fewer than 100 people, and are therefore small businesses as defined in the Regulatory Flexibility Act, N.J.S.A. 54:14B-16 et seq. Implementation of the proposed amendments, repeals and new rules may impose some additional requirements upon these facilities. However, as discussed in the Summary above, the proposed amendments and new rules do not establish a large number of completely new requirements as much as they attempt to make existing requirements more specific and bring them up-to-date. Consequently, while N.J.A.C. 8:43A-14 goes into considerable technical detail with respect to sterilization of patient care instruments, it does not mean that small ambulatory care facilities will have to contract this work out any more than at present. This will help to minimize the impact upon small businesses. Costs are discussed in the Economic Impact above. The amended and new rules were written with the intent of protecting patient health and safety without imposing unnecessary requirements on the facilities. Where the new rules do impose additional requirements, they are justified and necessary in order to protect the health and safety of New Jersey's citizens.

Smart Growth Impact

The proposed amendments, repeals and new rules will have no impact upon the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

Full text of the proposed repeals may be found in the New Jersey Administrative Code at N.J.A.C. 8:43A-14.3 through 14.7, and 17.1 through 17.6.

Full text of the proposed amendments and new rules follows (additions indicated in boldface and underlined **thus;** deletions indicated in brackets [thus]):

8:43A-3.7 Employee health.

(a) - (c) (No change.)

[(d) Each employee, including members of the medical staff employed by the facility, shall receive a Mantoux tuberculin skin test with five tuberculin units of purified protein derivative within six months of the effective date of this chapter. Each new employee shall be given a Mantoux tuberculin skin test upon employment. Subsequent tests shall be performed in accordance with facility policy. Employees who can document negative Mantoux skin test results (zero to nine millimeters of induration) within the last year, employees who can document positive Mantoux skin tests results (10 or more millimeters of induration), employees who have received appropriate medical treatment for tuberculosis, and employees for whom a Mantoux skin test is medically contraindicated shall not be required to receive a Mantoux tuberculin skin test.

1. If the Mantoux tuberculin skin test reaction is between zero and nine millimeters of induration, the test shall be repeated one to three weeks later.

2. If the Mantoux tuberculin skin test reaction is 10 or more millimeters of induration, a chest X ray shall be performed and, if necessary, followed by chemoprophylaxis or therapy.**]**

(d) Tuberculosis screening: The facility shall establish policies and procedures for the detection and control of the transmission of *M. tuberculosis* that include, but are not limited to, developing a Tuberculosis Exposure Control Plan (TB plan), according to the guidelines set forth in the Centers for Disease Control and Prevention's "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994," incorporated herein by reference, Morbidity and Mortality Weekly Report, (MMWR), published by the Epidemiology Program Office Centers for Disease Control and Prevention, October 28, 1994, Volume 43, Number RR-13, p. i-132, pursuant to the Occupational Safety and Health Act (OSH Act) of 1970, incorporated herein by reference and available by contacting the Superintendent of Documents, U.S. Government Printing Office, Washington DC, 20402-9325.

1. Newly hired employees: The facility shall establish policies and procedures that will identify a new employee's baseline status of exposure to *M. tuberculosis*. Upon employment, the facility shall administer a two-step Mantoux tuberculin skin test, using five tuberculin units of purified protein derivative, to all employees. Employees are defined for the purposes of this section as full and part-time employees, volunteer staff, and physicians, either salaried by the facility or with clinical privileges to provide medical care at the facility.

i. Employees with a "negative" (less than 10 mm of induration or less than five mm of induration if the individual is immunosupressed) result following the first Mantoux skin test are administered a second test in one to three weeks.

ii. Employees with a "positive" (greater than 10 mm of induration or greater than five mm of induration if the individual is immunosupressed) result following either the first or second test are referred for a medical evaluation to determine whether there is evidence of latent tuberculosis infection or active tuberculosis disease.

(1) The medical evaluation shall include, but is not limited to, a chest X-ray.

(2) The facility shall permit employees with positive Mantoux test results to begin working after the employee has submitted written medical clearance to the facility.

iii. Exceptions:

(1) Employees who provide documentation of negative results of a single Mantoux skin test performed within the 12 months preceding the start of employment shall receive only one Mantoux skin test upon hire.

(2) Employees with prior documentation of negative results of two Mantoux skin tests performed within 12 months of preceding start of employment, and without signs and symptoms of active tuberculosis, shall not be required to be tested upon hire; however, a Mantoux skin test shall be required within 12 months of the last tuberculin skin test.

(3) Employees who provide documentation of positive Mantoux skin test results shall be exempt from screening.

(4) Employees who provide documentation of having received and completed appropriate medical treatment for active tuberculosis disease or latent tuberculosis infection shall be exempt from screening.

2. Periodic screening of personnel: The facility shall establish policies and procedures for the periodic screening of Mycobacterium tuberculosis in eligible personnel, including, but not limited to:

i. Testing: The facility shall administer a Mantoux skin test to all tuberculin-negative employees annually at minimum. Frequency of testing shall be determined by the level of risk assigned by the facility's TB plan.

ii. Recordkeeping: The facility shall submit the results of employee Mantoux tuberculin testing bi-annually to the New Jersey Department of Health and Senior Services, on forms provided by the Department, at the address listed below.

3. Further information: Questions regarding tuberculosis control may be directed to:

New Jersey Department of Health and Senior Services
Tuberculosis Program
PO Box 369
Trenton, NJ 08625-0369
(609) 588-7522

(e) (No change.)

SUBCHAPTER 14. INFECTION PREVENTION AND CONTROL SERVICES

8:43A-14.1 Administrator's responsibilities

(a) The administrator**, or designee,** shall ensure the development and implementation of an infection prevention and control program.

(b) The administrator shall designate **[**a person with a health care background**]** **an infection control professional** who shall be responsible for the direction, provision, and quality of infection prevention and control services. The designated person shall be responsible for, but not limited to, developing and maintaining written objectives, **[**a policy and procedure manual**]** **policies and procedures**, an organizational plan, and a quality **[**assurance**]** **improvement** program for the infection prevention and control service. **[**If the facility provides primary care, hospital outpatient, ambulatory surgical, or chronic dialysis services, the designated person shall have had training or experience in surveillance, prevention, and control of nosocomial infection.**]** **The infection control professional may be a consultant; however, there must be a health care professional on site who is responsible for the day to day activities related to infection control.**

(c) The infection control professional shall have education or training in surveillance, prevention, and control of nosocomial infections. The infection control professional shall be certified in infection control within five years of beginning practice of infection control and shall maintain certification through the Certification Board of Infection Control (CBIC).

8:43A-14.2 Infection control policies and procedures

(a) The facility shall establish an infection control committee which shall include the medical director**, the infection control professional,** and representatives from at least administration and the nursing service. **If this facility is owned or operated by an acute care hospital, then the facility may participate in the hospital's infection control program.**

(b) The infection control committee, with assistance from each service in the facility, shall develop, implement, and review, **[**at least annually**]** **every three years or more frequently as necessary**, written policies and procedures regarding infection prevention and control, including, but not limited to, policies and procedures regarding the following:

1. (No change.)

2. Identifying and reporting of HIV/AIDS as specified in N.J.A.C. 8:57-2.7, Reporting of Acquired Immunodeficiency Syndrome and Infection with Human Immunodeficiency Virus;

Recodify existing 2. - 4. as **3. – 5.** (No change in text.)

[5.] **6.** Aseptic technique, employee health in accordance with N.J.A.C 8:43A-3.7, and staff training **in regard to infection control**;

[6.] **7.** (No change in text.)

[7.] **8.** Exclusion from work, and authorization to return to work, for personnel with communicable diseases; **and**

[8.] **9.** Surveillance techniques to **[**minimize**]** **identify** sources and **minimize** transmission of infection **[**;**]** **.**

[9. Sterilization, disinfection, and cleaning practices and techniques used in facility, including, but not limited to the following:

i. Care of utensils, instruments, solutions, dressings, articles, and surfaces; and

ii. Selection, storage, use, and disposition of single use and other patient care items;

10. Collection, handling, storage, decontamination, disinfection, and disposal of regulated medical waste and all other solid or liquid waste.**]**

8:43A-14.3 Infection prevention measures

[(a) The facility shall follow all Category I recommendations in the current editions of the following Centers for Disease Control publications, as amended and supplemented, incorporated herein by reference, unless the facility infection control committee makes a documented exception for a specific guideline:

1. Guideline for Prevention of Catheter-Associated Urinary Tract Infections;

2. Guideline for Prevention of Intravascular Infections;

3. Guideline for Prevention of Surgical Wound Infections;

4. Guideline for Prevention of Nosocomial Pneumonia; and

5. Guideline for Handwashing and Hospital Environmental Control.

(b) The guidelines listed in (a) above may be obtained from the Centers for Disease Control, Atlanta, Georgia 30333, or the sources listed at N.J.A.C. 8:43A-14.2.**]**

(a) Infection prevention activities shall be based on Centers for Disease Control and Prevention Guidelines, and Hospital Infection Control Practices Advisory Committee (that is, HICPAC) recommendations. An exception to the adoption of the following guidelines shall be allowed providing that there is a sound infection control rationale based upon scientific research or epidemiologic data. The following published guidelines and recommendations are incorporated herein by reference, as amended and supplemented:

1. Guideline for Prevention of Catheter-Associated Urinary Tract Infections (1981);

2. Guideline for Prevention of Intravascular Device-Related Infections (Infection Control and Hospital Epidemiology 1996; 17: 438-73 and American Journal of Infection Control 1996; 24: 262-93);

3. Guidelines for Prevention of Surgical Site Infections (1999) (Infection Control and Hospital Epidemiology 1999; 20: 247-278);

4. Guideline for Prevention and Control of Nosocomial Pneumonia (American Journal of Infection Control, August 1994; 22:247-92 and Infection

Control and Hospital Epidemiology, September 1994; 15: 587-627 and Respiratory Care, December 1994; 39: 1191-1236;

5. Guideline for Handwashing and Hospital Environmental Control (1985);

6. Guideline for Infection Control in Hospital Personnel (1998);

7. Guideline for Isolation Precautions in Hospitals (Infection Control and Hospital Epidemiology 1996; 17:53-80 and the American Journal of Infection Control 1996; 24:24- 52)

8. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health Care Facilities (Morbidity and Mortality Weekly Report 1994; 43: 11-22); and

9. HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance. (Infection Control and Hospital Epidemiology 1995; 16: 105-113)

(b) The guidelines listed in (a) above are available from the National Technical Information Service (NTIS) by calling 1-800-553-6847 or writing the NTIS, 5285 Port Royal Road, Springfield, Virginia 22161. The complete set of the seven Guidelines for the Prevention and Control of Nosocomial Infections are listed under the publication number: PB86133022. Further information is available on the Centers for Disease Control and Prevention National Center of Infectious Diseases web site at: http://www.cdc.gov/ncidod/hip. The HICPAC Recommendations for Preventing the Spread of Vancomycin Resistance is available on the CDC web site at: http://www.cdc.gov/ncidod/vancom.htm. CDC's Hospital Infections Program's Methicillin-resistant Staphylococcus Aureus: Facts for Healthcare Workers is available at: http://www.cdc.gov/ncidod/hip/aresist/mrsahcw.htm

8:43A-14.4 Sterilization of patient care items

(a) Methods for processing reusable medical devices shall conform with the following documents, incorporated herein by reference, as amended and supplemented;

1. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Good Hospital Practice: Steam Sterilization and Sterility Assurance," ST 46;

2. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use," ST 37;

3. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Safe Use and Handling of Gultaraldehyde-based Products in Health Care Facilities," ST 58;

4. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Guidelines for the Selection and use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities," ST 33;

5. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Steam Sterilization and Sterility Assurance Using Table Top Sterilizers in Office-Based, Ambulatory Care, Medical, Surgical and Dental Facilities," January 1998; ST-42R;

6. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Safe handling and biological decontamination of medical devices in health care facilities and in nonclinical settings," ST 35;

7. The Association for the Advancement of Medical Instrumentation (AAMI) requirements, "Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness," October 1998, ST 41R; and

8. Society of Gastroenterology Nurses and Associates (SGNA), "Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes," (2000).

(b) The documents referenced in (a) are reviewed and/or revised every five years or more frequently as needed; the most current document is to be used. The AAMI requirements can be obtained from: The Association for the Advancement of Medical Instrumentation, 3330 Washington Building, Suite 400, Arlington, VA 22209 or at the AAMI website at www.aami.org. SGNA's Standards and Guidelines are available from the Society of Gastroenterology Nurses and Associates, Inc., 401 North Michigan Ave., Chicago, Il 60611-4267, or at www.sgna.org.

(c) Emphasis shall be placed on cleaning of these devices prior to sterilization or disinfection. The selection and use of disinfection and/or sterilization methods for patient care items or equipment shall be divided into the following three categories:

1. Critical items are objects that enter sterile tissue or the vascular system. These instruments, excluding scopes, must be sterilized by a process that can demonstrate a sterility assurance level of 10^{-6}.

i. Laparoscopes, arthroscopes, and other scopes that enter normally sterile areas of the body shall be sterilized or given high-level disinfection after each use according to the manufacturers' written recommendations or according to policy established by the facility's infection control committee.

2. Semicritical items are objects which come into contact with mucous membranes or with skin that is not intact. Semicritical items require high level disinfection or intermediate level disinfection. (At a minimum the disinfectant must be labeled as tuberculocidal.)

3. Noncritical items are objects that come into contact with intact skin but not with mucous membranes. Noncritical items shall at a minimum be exposed to a low level disinfectant.

(d) The efficacy of chemicals used for high-level disinfection shall be verified by the use of a test method specific to the chemical if a valid and reliable test method is available and feasible for use in an ambulatory setting.

(e) At the completion of each sterilization cycle, the following documentation shall be recorded and maintained on site for at least one year:

1. Time, temperature and pressure readings shall be verified and the print out/chart initialed by the operator before items are removed; and

2. A record of each sterilization/disinfection load, including the date, load/cycle number and the specific contents of the load shall be retained for a least one year or per facility policy, whichever is greater.

(f) Each package shall be labeled with sterilization date and load number.

(g) The manufacturer's instructions for cleaning, testing, disassembly, and sterilization of equipment shall be readily available and followed by employees.

1. All hinged instruments shall be processed in an open position.

2. All instruments that can be disassembled shall be disassembled for decontamination and sterilization.

(h) Sterilized materials shall be stored, handled and transported to maintain sterility. Package integrity shall be maintained until used.

(i) Sterile supplies which bear an expiration date shall not exceed the shelf life date as recommended by the manufacturer of the packaging selected or the device contained therein.

1. A policy and procedure to retrieve and reprocess outdates shall be established and enforced.

(j) If the facility is using an event-related sterility program, the process shall include a continuous quality plan with documentation of facility compliance with the following:

1. Proper transportation of sterile product;

2. Proper storage conditions of sterile product;

3. Proper rotation of sterile product; and

4. Maintenance of sterile pack integrity.

(k) All sterilization equipment shall be installed and operated in accordance with the sterilizer manufacturer's written instructions.

(l) Single use patient care items shall be reprocessed under the following conditions:

1. The manufacturer provides written documentation for cleaning and sterilization of the item and the facility has the resources to meet those specifications;

2. Methods for processing single use patient care items conform with the following Food and Drug Administration regulations:

i. Premarket Notification, Registration and Listing shall comply with 21 CFR, Part 807, incorporated herein by reference, as amended and supplemented; and

ii. Quality system regulations as specified in 21 CFR Part 807, incorporated herein by reference, as amended and supplemented; and

3. If the facility retains an outside firm to perform its sterile reprocessing, a quality control program shall be established to ensure the delivery of a safe product as specified in the contract with the third party processor.

(m) Shared reprocessing by outside healthcare reprocessing centers shall meet the following standards:

1. Policies and procedures for all processing protocols shall be approved by all facilities in the network in conjunction with infection control managers.

2. Instruments and devices transported off site for processing shall be inventoried and pre-cleaned prior to transportation.

i. Soiled instruments shall be contained in impervious, closed containers which are either locked or sealed in covered carts.

3. All decontamination, assembly and sterilization shall be performed according to the device manufacturer's written recommendations.

i. Manufacturer's written instructions for processing of all specialty devices shall be obtained, followed and kept on file at the processing facility.

4. The following records shall be maintained at the processing facility:

i. Sterilization logs shall be maintained for all items sterilized; and

ii. Biological monitoring as specified in N.J.A.C. 8:43A-14.5(a).

5. Immediate notification shall be made to the receiving facility upon a positive biological result.

6. Transport of sterile product shall be performed using disinfected, impervious containers that are either locked or sealed in covered carts.

8:43A-14.5 Care and use of sterilizers, ethylene oxide, peracetic acid, low temperature gas, plasma, and steam

(a) Biological monitoring with live spores, or an FDA approved equivalent, shall be performed as follows:

1. Ethylene oxide - in each load;

2. Peracetic acid – weekly;

3. Low temperature gas plasma - daily in the working load;

4. Steam sterilizers – weekly;

5. A biological monitor with live spores shall be performed following repair or breakdown of the above mentioned equipment; and

6. A biological monitor, or spore based enzyme, shall be used with each load containing implantables, and the implantable device shall not be used until the negative biological test is received.

(b) The biological indicator shall be applicable for the process used and shall be stored and used in accordance with the manufacturer's recommendations.

1. A rapid read out biological monitor must be incubated to obtain a spore kill reading. The length of incubation shall comply with the written instructions provided by the manufacturer of the biological indicator.

2. A chemical indicator/integrator, applicable to the sterilization process used, shall be used in the following:

i. Each package processed in steam.

ii. Each package processed in ethylene oxide.

iii. Each package processed in low temperature gas plasma.

iv. Each load, as directed by the manufacturer, for peracetic acid.

3. A prevacuum air removal test shall be performed daily on each prevacuum sterilizer and following repair or breakdown of the prevacuum sterilizer.

4. In the event of positive biological test results on a sterilizer, effective corrective action shall be taken including retesting and recalls if indicated.

i. Documentation of actions taken shall be maintained on site.

ii. There shall be an established recall system in effect.

5. The individual responsible for reprocessing reusable medical instruments shall be certified by a national central service certification program upon hire or within two years of employment.

6. All personnel involved in the use of ethylene oxide shall have the appropriate licensure from the New Jersey Department of Environmental Protection (NJDEP).

8:43A-14.6 Maintenance of sterile processing environment

(a) The following environmental surfaces shall be maintained as follows in decontamination and clean processing areas.

1. Hard surface floors shall be kept clean.

2. Walls shall be cleaned of spills and splashes as necessary.

3. Ceilings, ventilation system vents, and sterilizer vents shall be clean and free from dust.

4. Storage shelves shall be kept clean.

5. All horizontal surfaces shall be disinfected each shift and as needed.

(b) There shall be separation between clean and contaminated work areas and activities.

8:43A-14.7 Infection control quality improvement methods

The infection control professional shall develop and implement a program of quality improvement that is integrated into the facility quality improvement program and includes regularly collecting and analyzing data to help determine the effectiveness of infection control practices. When corrective actions need to be taken based on data collected, the infection control committee shall recommend, implement, and monitor those actions. The infection control professional shall supervise these quality improvement activities. These quality

improvement activities shall be overseen by the continuous quality improvement program. (See Subchapter 18).

SUBCHAPTER 17. HOUSEKEEPING, SANITATION AND SAFETY

8:43A-17.1 Housekeeping policies and procedures

(a) The housekeeping service shall have written policies and procedures that are reviewed every three years or as needed, revised as needed, and implemented. They shall include, at least, scope of responsibility, assignment by designated unit, and responsibility for all cleaning tasks.

(b) The housekeeping service shall have a written schedule that determines the frequency of cleaning and maintaining cleanliness for all equipment, structures, areas, and systems within its scope of responsibility.

(c) There shall be a list available at all times of all cleaning and disinfecting agents used in the facility together with their Materials Safety Data Sheets (MSDS).

(d) Records of all pesticides and herbicides used at the facility shall be maintained on-site, together with their Materials Safety Data Sheets (MSDS).

(e) All cleaning and disinfecting agents shall be correctly labeled with the name of the product and its use, as specified by the manufacturer, including agents that have been repackaged from a bulk source.

(f) All pesticides shall be applied in accordance with State Pesticide Control Code, N.J.A.C. 7:30.

8:43A-17.2 Housekeeping staff

(a) There shall be an individual responsible for the housekeeping or environmental services. This individual may be a contracted provider.

(b) Housekeeping personnel shall be trained upon hire and on an annual basis or more frequently as necessary. Training should focus on cleaning procedures, including the selection and use of appropriate chemicals in the cleaning and care of equipment and surfaces.

8:43A-17.3 Housekeeping patient services

(a) All areas, including areas with limited access such as cabinet, drawers, locked medication rooms, and storage areas, shall be kept clean to sight and touch and free of condensation, mold growth and noxious odors.

(b) All equipment and materials necessary for cleaning, disinfecting, and sterilizing (if applicable) shall be provided.

(c) All household and cleaning products in the facility shall be identified, labeled, and securely stored in a cabinet, closet, or room which is inaccessible to patients.

(d) Housekeeping and cleaning supplies shall be selected and approved by the Infection Control Committee. They shall be measured and used correctly according to the manufacturers' written instructions.

(e) All toilets and bathrooms shall be kept clean to sight and touch, in good repair, and free of odors that reflect poor housekeeping practices.

(f) Toilet tissue, soap, and disposable towels or air driers shall be provided in each bathroom at all times. Soap and disposable towels or air driers shall be provided at each handwashing sink at all times.

(g) Reusable hand-cleanser dispensers shall be clean inside and out. Disposable dispensers shall be discarded and not refilled.

(h) Carpeting shall be kept clean and odor-free and shall not be frayed, worn, torn, or buckled.

(i) Window and partitioning curtains and drapes shall be kept clean to sight and touch and odor-free.

(j) Walls, ceilings, and vents shall be kept clean to sight and touch and odor-free.

(k) Windows and screens shall be kept clean to sight and touch and in good repair.

(l) Effective and safe controls shall be used to minimize and eliminate the presence of rodents, flies, roaches and other vermin in the facility. The premises shall be kept in such condition as to prevent the breeding, harborage, or feeding of vermin. All openings to the outer air shall be effectively protected against the entrance of insects.

(m) Nonskid wax shall be used on all waxed floors.

(n) All communal toys shall be washed after each use. No stuffed animals shall be allowed except for personal use.

(o) Plants and flowers shall not be allowed in patient treatment areas (such as operating rooms and procedure rooms) or sterile processing areas.

8:43A-17.4 Environmental patient care services

(a) The following environmental conditions shall be met:

1. Thermometers which are accurate to within three degrees Fahrenheit shall be kept in a visible location in refrigerators, freezers, and storerooms used for perishable and other items subject to deterioration. Records shall be kept for 12 months;

2. Articles in storage shall be elevated from the floor and away from walls, ceilings, and air vents to facilitate cleaning. Storage units shall be non-porous and cleanable;

3. There shall be separate refrigerators for medications, laboratory specimens, and food. There shall be a separate designated area for all food items and beverages. Records shall be kept for 12 months;

4. Draperies, upholstery, and other fabrics or decorations shall be fire-resistant and flameproof;

5. Latex foam pillows shall be prohibited;

6. Equipment requiring drainage shall be drained to a sanitary connection, in accordance with State and local codes;

7. During warm weather conditions, the temperature of the facility shall not exceed 82 degrees Fahrenheit. The facility shall establish a written heat emergency action plan which specifies procedures to be followed in the event that the indoor air temperature is 82 degrees Fahrenheit or higher for a continuous period of four hours or longer. The facility shall provide adequate ventilation in all areas used by patients;

8. The temperature in the facility shall be kept at a minimum of 72 degrees Fahrenheit (22 degrees Celsius) when patients are in the facility;

9. Throw rugs or scatter rugs shall not be used in the facility;

10. All equipment shall have unobstructed space provided for operation;

11. Combustible materials shall not be stored in heater rooms or within 18 feet of any heater located in an open basement;

12. Paints, varnishes, lacquers, thinners, and all other flammable materials shall be stored outside the building. Minimum supplies may be kept in the

building in a locked storage room or in closed, locked metal cabinets or containers in a non-patient area of the facility;

13. All furnishings shall be clean and in good repair, and mechanical equipment shall be in good working order. Equipment shall be kept covered to protect from contamination and accessible for cleaning and inspection. Broken or worn items shall be repaired, replaced, or removed promptly;

14. Mattresses, mattress pads and coverings, pillows, bedsprings, and other furnishings shall be properly maintained and kept clean. They shall be thoroughly cleaned and disinfected upon discharge of each patient;

15. All equipment and environmental surfaces shall be kept clean to sight and touch; and

16. When areas of the facility are undergoing renovation or new construction, protective measures shall be taken to contain dust and redirect traffic in patient care areas.

8:43A-17.5 Regulated medical waste and solid waste management

(a) Policies and procedures for solid waste and recyclables shall be established and enforced to ensure appropriate collection, storage and disposal and to maintain them clean and odor-free and to prevent the breeding of insects or vermin.

1. Plastic bags shall be used for solid waste removal from patient care units and support departments. Bags shall be of sufficient strength to safely contain waste from point of origin to point of disposal and shall be effectively closed prior to disposal.

2. Outside storage containers for solid waste shall be kept covered, except those used for corrugated cardboard, recyclables, or construction materials.

3. Garbage compactors shall be located on an impervious pad that is graded to a drain. The drain shall be kept clean and shall be connected to the sanitary sewage disposal system.

4. All solid waste that is not regulated medical waste shall still be disposed of in a manner approved by the New Jersey Department of Environmental Protection. Disposal shall be as frequent as necessary to avoid creating a nuisance.

5. Indoor storage containers for solid waste shall be fireproof and kept covered when necessary to control odors or other nuisances.

6. Solid waste shall be stored within the containers provided for it in an area that is kept clean. Waste shall be collected from the storage area regularly to prevent nuisances such as odors, flies, other vermin, or rodents, and so that waste does not overflow or accumulate beyond the capacity of the storage containers.

(b) The facility shall comply with the provisions of N.J.S.A. 13:1E-48.1 et seq., the Comprehensive Regulated Medical Waste Management Act, and all rules promulgated pursuant to the aforementioned act.

(c) All liquid waste shall be collected, stored, and disposed of in accordance with the rules of the New Jersey Department of Environmental Protection.

8:43A-19.8 Construction and renovation

(a) Whenever construction and renovation projects are planned in and around a health care facility, a risk assessment shall be conducted to determine the impact of the project on patient areas, personnel, and mechanical systems.

1. The infection control program shall review areas of potential risk and populations at risk. The infection control program shall approve control measures, if necessary.

(b) The design phase shall include commissioning specifications of ventilation requirements used during and at completion of the construction project.

(c) An education program shall be established for facility employees of the areas affected, the contractor's employees, and the contractor to define the impact, risks, interventions and compliance issues.

SUBCHAPTER 31. WATER SUPPLY AND LAUNDRY

8:43A-31.1 Water supply

(a) The water supply used for drinking or culinary purposes shall be adequate in quantity, of a safe and sanitary quality, and from a water system which shall be constructed, protected, operated, and maintained in conformance with the New Jersey Safe Drinking Water Act, N.J.S.A. 58:12A-1 et seq., N.J.A.C. 7:10, and local laws, ordinances, and regulations. There shall be no back siphonage conditions present. Copies of the Safe Drinking Water Act can be obtained from the New Jersey Department of Environmental Protection, Bureau of Potable Water, P.O. Box 209, Trenton, New Jersey 08625-0209.

(b) Hot running water (between 105 and 120 degrees Fahrenheit or 41 to 49 degrees Celsius) and cold running water shall be provided in patient care areas.

8:43A-31.2 Laundry policies and procedures

(a) The laundry service shall have written policies and procedures, which are reviewed every three years or more frequently as needed, revised as needed and implemented. The written policies and procedures shall include a policy that identifies special handling practices for soiled laundry.

(b) All used laundry shall be considered contaminated and handled according to the facility's written policies and procedures, as approved by the infection control committee.

8:43A-31.3 Laundry patient services

(a) All soiled laundry from patient care areas shall be collected and transported in a manner to prevent any leakage.

(b) Laundry carts shall be in good repair, kept clean, and identified for use with either clean linen or soiled laundry.

(c) Clean linen shall be transported in covered carts and stored in a covered or enclosed area.

(d) Bedding (sheets, pillowcases, drawsheets, and blankets) and clothing provided to staff and patients shall be clean and in good repair.

(e) Mop heads shall be washed separately from all other laundry. A wash cycle using bleach shall be used after each mop head washing, unless the washing machine is dedicated to mop heads only.

8:43A-31.4 Laundry space and environment

(a) Soiled laundry shall be stored in containers provided for it in a clean, ventilated, vermin-proof and vermin-free area, separate from other supplies. It shall be collected from the storage area regularly so that it does not overflow or accumulate beyond the capacity of the storage containers.

(b) Soiled laundry shall be stored, sorted, rinsed, and laundered only in areas specifically designated for those purposes.

(c) If a laundry chute is used, it shall be kept locked.

(d) If a laundry chute is used, it shall be maintained in good repair and cleaned, and there shall be no build-up of visible soil.

(e) Laundry chutes shall empty into an enclosed room.

(f) If the facility has an in-house laundry for the bulk of the facility's linens, it shall provide a receiving, holding, and sorting area with handwashing facilities. The walls, floor and ceiling of the area shall be kept clean and in good repair.

(g) If the facility has a limited-use, home-style laundry (for example, for laundering items such as cubicle curtains), the walls, floor, and ceiling of the area shall be kept clean and in good repair.

(h) If the facility contracts with a commercial laundry service, the facility shall have areas for sorting and receiving laundry. These areas shall be kept clean and in good repair.

(i) A written schedule shall be developed and implemented for removing lint from laundry areas on a routine basis.

(j) If the facility has an in-house laundry, the flow of ventilating air shall be from clean to soiled areas, and ventilation shall be adequate to prevent odor build-up. Soiled laundry and clean linen shall be kept separate.

8:43A-31.5 Laundry supplies and equipment

(a) The facility shall have on-site an adequate supply in good repair of sheets, pillowcases, drawsheets, blankets, towels, washcloths, and scrub suits.

(b) All facilities shall provide laundered scrub suits in the following areas: surgical suites, obstetrical surgical suites, stage one postanesthesia care units, central processing, and those areas as determined by facility policy.

(c) If the facility has an in-house laundry, an established protocol shall be followed to reduce the number of bacteria in the fabrics. Equipment and surfaces that come into contact with soiled laundry and clean linen shall be sanitized.

(d) The laundry service shall monitor and document at least the following:

1. Unsafe objects found;

2. Linen supply;

3. Stained linens; and

4. pH. A random sample of all laundry batches from all sources shall be sour tested to ensure neutralization of alkaline residues from built detergents. Sour testing is a test performed to indicate the degree of acidity or alkalinity of linens. Built detergents are a mixture of one or more alkaline detergents that contains not less than 50 percent anhydrous soap (pure soap, free from water).

Fabric pH shall be maintained at 7.0 or below after souring when built detergents are used.

8:43A-31.6 Laundry staff education and training

(a) If applicable, requirements for the laundry staff education program shall be as provided in N.J.A.C. 8:43G-5.9.

(b) If applicable, orientation for new laundry employees shall include protocols for handling and receiving soiled laundry and clean linen.

8:43A-31.7 Laundry quality improvement methods

(a) There shall be a program of quality improvement for the laundry service that is coordinated with the facility quality improvement program and includes regularly collecting and analyzing data to help identify problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data. (See N.J.A.C. 8:43A-18, Quality Assurance Program).

(b) Facilities which contract with a commercial laundry service shall use quality improvement measures to ensure that the standards of N.J.A.C. 8:43A-31.2 through this section are met.